

RESPONSE TO RESTRICTION REQUIREMENT
U.S. Appln. No. 10/528,364 (Q86490)

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application:

LISTING OF CLAIMS:

Claim 1. (Currently Amended) A process for the production of a vaccine composition of labile immunogens, ~~wherein a fluid comprising:~~

(A) spraying a fluid comprising one or more liable immunogens ~~is sprayed~~ into a reactor containing fluidized particles of a pharmaceutically acceptable water—soluble material at a temperature of about 25°C to about 50°C, such that the immunogen(s) coats and is dried onto the fluidized particles under the fluidizing conditions, and thereafter

(B) -collecting from said reactor, dried immunogen ~~containing~~ coated particles having a moisture content between about 0.1% w/w to about 10% w/w so as to give a stabilized vaccine composition.

Claim 2. (Currently Amended) ~~A~~The process according to claim 1, wherein the immunogen comprises a member selected from the group consisting of virus particles, bacterial cells, ~~or~~ other microorganisms, and ~~or~~ antigenic products thereof.

Claim 3. (Currently Amended) ~~A~~The process according to claim 2, wherein the immunogen comprises virus particles or bacterial cells.

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Claim 4. (Currently Amended) ~~A~~The process according to claim 2, wherein the immunogen comprises a viral or bacterially derived immunogen selected from the group consisting of a protein, peptide, glycoprotein, ~~or~~ glycolipid, ~~or~~and polysaccharide, optionally associated with a carrier, which on immunization of a subject provokes an immune response to the virus or bacteria from which the immunogen was derived.

Claim 5. (Currently Amended) ~~A~~The process according to claim 1, wherein the fluid comprising one or more immunogens is a viral vaccine or bacterial vaccine preparation mixed with a ~~stabilising~~stabilizing diluent to provide a fluid comprising viral particles or bacterial immunogens.

Claim 6. (Currently Amended) ~~A~~The process according to claim 1, wherein the temperature is from about 30°C to about 46°C.

Claim 7. (Currently Amended) ~~A~~The process according to claim 1, wherein the moisture content is from 0.1% w/w to 2.6% w/w.

Claim 8. (Currently Amended) ~~A~~The process according to claim 7, wherein the moisture content is from 0.2% w/w to 1.5% w/w.

Claim 9. (Currently Amended) ~~A~~The process according to claim 1, wherein said fluid comprising one or more immunogens is a suspension or dispersion of immunogens selected from the group consisting of viral particles, bacterial cells, ~~or~~ other microorganisms, eukaryotic cells, ~~and~~or antigenic products of said immunogens.

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Claim 10. (Currently Amended) AThe process according to claim 1, wherein said fluid ~~containing~~ comprising one or more immunogens ~~includes~~ comprises one or more amino acids, proteins, chelating agents, buffers, preservatives, stabilizers, mineral salts, metal antioxidants, lubricants and adjuvants.

Claim 11. (Currently Amended) AThe process according to claim 9, wherein viral particles or bacterial cells in a culture medium, vaccine composition or other fluid are diluted with a diluent.

Claim 12. (Currently Amended) AThe process according to claim 1, wherein said particles of a pharmaceutically acceptable water—soluble material comprise one or more members selected from the group consisting of monosaccharide, disaccharide, polysaccharide, carbohydrate, water—soluble peptide, mineral salt, water—soluble polymer, ~~or~~ and water—soluble pharmaceutically acceptable excipient.

Claim 13. (Currently Amended) AThe process according to claim 1, wherein said pharmaceutically acceptable water—soluble material comprises one or more sugars.

Claim 14. (Currently Amended) AThe process according to claim 1, wherein the pharmaceutically acceptable water—soluble material ~~has~~ comprises a particle size of from 20 microns to 1—mm.

Claim 15. (Currently Amended) AThe process according to claim 14, wherein said particle size is from 50 microns to 200 microns.

Claim 16. (Currently Amended) AThe process according to claim 1, wherein said reactor is a spray drying reactor of a

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fluidized bed into which immunogen containing fluid is sprayed onto fluidized particles and dried thereon.

Claim 17. (Currently Amended) AThe process according to claim—16, wherein fluid comprising one or more immunogens is sprayed through a nozzle or spray head which delivers the sprayed fluid into the reactor.

Claim 18. (Currently Amended) AThe process according to claim 16, wherein said particles are fluidized in a reactor containing a fluidized bed at a rate between 200 to 500 m²/h.

Claim 19. (Currently Amended) AThe process according to claim 1, wherein said ~~stabilized~~-vaccine composition is stable and efficacious on storage at 25°C for 30 days.

Claim 20. (Currently Amended) AThe process according to claim 1, wherein the vaccine composition is a free flowing particulate material.

Claim 21. (Currently Amended) AThe process according to claim 1, which further comprises mixing together two or more ~~free flowing stabilized of said vaccine~~ compositions containing different immunogens to give a multivalent vaccine composition.

Claim 22. (Currently Amended) AThe process according to claim 3, wherein said virus particles or bacterial cells ~~are~~ is a carrier for the delivery of DNA sequences, RNA sequences or vaccine antigens.

Claim 23. (Currently Amended) AThe process according to claim 3, wherein said virus particles or bacterial cells are genetically modified.

Claim 24. (Currently Amended) A stabilized vaccine composition comprising immunogen coated particles of a

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pharmaceutically acceptable water--soluble material, wherein the composition having ~~has~~ a moisture content of between about 0.1% w/w to about 10% w/w.

Claim 25. (Currently Amended) AThe stabilized vaccine composition according to claim 24, wherein the immunogen comprises a member selected from the group consisting of virus particles, bacterial cells, ~~or~~ other microorganisms ~~or~~ and antigenic products thereof.

Claim 26. (Currently Amended) AThe stabilized vaccine composition according to claim 24, wherein the immunogen comprises virus particles or bacterial cells.

Claim 27. (Currently Amended) AThe stabilized vaccine composition according to claim 26, wherein the composition ~~which~~ contains live virus particles capable of reproduction in an immunized host.

Claim 28. (Currently Amended) AThe stabilized vaccine composition according to claim 24, wherein the immunogen comprises a viral or bacterially derived immunogen selected from the group consisting of a protein, peptide, glycoprotein, ~~or~~ glycolipid, ~~or~~ and polysaccharide, optionally associated with a carrier, which on immunization of a subject provokes an immune response to the virus or bacteria from which the immunogen was derived.

Claim 29. (Currently Amended) AThe stabilized vaccine composition according to claim 24, ~~which~~ wherein said composition is stable and efficacious on storage at 25°C for 30 days.

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Claim 30. (Currently Amended) AThe stabilized vaccine composition according to claim 24, wherein the pharmaceutically acceptable ~~water~~ water-soluble material comprises one or more members selected from the group consisting of a monosaccharide, disaccharide, polysaccharide, ~~or~~ carbohydrate, ~~water--soluble~~ peptide ~~or peptides~~, gelatine, mineral salt, ~~or~~ water--soluble polymer, ~~or and~~ water--soluble pharmaceutically acceptable excipient.

Claim 31. (Currently Amended) AThe stabilized vaccine composition according to claim 30, wherein said ~~water--soluble~~ material comprises one or more sugars.

Claim 32. (Currently Amended) AThe stabilized vaccine composition according to claim 24, wherein said composition comprises ~~comprising~~ two or more different immunogen coated particles, so as to give a multivalent vaccine.

Claim 33. (Currently Amended) AThe stabilized vaccine composition according to claim 24, wherein the immunogen is a carrier of a nucleic acid sequence or a peptide or polypeptide.

Claim 34. (Currently Amended) AThe stabilized vaccine composition according to claim 24, wherein said composition ~~which comprises~~ has a particle size from 50 microns to 400 microns.

Claim 35. (Currently Amended) AThe stabilized vaccine composition ~~process~~ according to claim 34, wherein said particle size is from 50 ~~microns~~ to 200 microns.

Claim 36. (Currently Amended) AThe stabilized vaccine composition according to claim 24, wherein said immunogen coated particles comprise ~~include~~ one or more members selected from the

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group consisting of amino acids, proteins, chelating agents, buffers, preservatives, stabilizers, mineral salts, antioxidants, lubricants and adjuvants.

Claim 37. (Currently Amended) ~~A~~The stabilized vaccine composition according to claim 24, wherein said composition ~~which~~ is a free flowing particulate composition.

Claim 38. (Currently Amended) ~~A~~The stabilized vaccine composition according to claim 24, wherein said composition ~~which~~ is immunogenic on administration to an animal or human.

Claim 39. (Currently Amended) ~~A~~The stabilized vaccine composition according to claim 24, wherein said composition ~~which~~ is a human or animal vaccine.

Claim 40. (Currently Amended) ~~A~~The stabilized vaccine according to claim 39, wherein said composition ~~which~~ is a poultry vaccine for the prevention or treatment of Newcastle Disease, infectious bronchitis, coccidiosis, fowl pox, fowl cholera, reovirus induced tenosynovitis (viral arthritis), fowl laryngotracheitis, avian encephalomyelitis, infectious bursal disease (IBD), Marek's Disease, salmonella infection, mycoplasma gallisepticum infection, avian rhinotracheitis, avian herpes and *Mycoplasma hyponeumoniae*, Egg Drop Syndrome, Infectious Coryza (*Haemophilis pasagallinarum*), mycoplasma synoviae or avian reovirus.

Claim 41. (Currently Amended) ~~A~~The stabilized vaccine composition according to claim 39, wherein said composition is a porcine vaccine, for the prevention or treatment of *Actinobacillus pleuropneumoniae*, atrophic rhinitis, pseudorabies, swine erysipelas, porcine parvovirus,

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~~E. coli~~ E. coli enterotoxigenesis, myoplasma hyopneumoniae, influenza, leptospira, ~~E. coli~~ E. coli infection, Porcine Reproductive and Respiratory Syndrome (PRRS), Bordetella and multocida types A and D infections, haemophilus parasuis infection, clostridium perfringens infection, rotavirus infection, Streptococcus suis infection, Glasser's Disease, pneumonia, or bordetella bronchiseptica infection.

Claim 42. (Currently Amended) A The stabilized vaccine according to claim 39, wherein said composition ~~which~~ is a human vaccine for the prevention or treatment of influenza, hepatitis A, hepatitis B, hepatitis C, herpes simplex virus (type 2), polio, diphtheria, pertussis, haemophilus influenza type B (Hib), measles, mumps, rubella, typhoid fever, varicella (chicken pox), Dengue fever, Epstein-Barr virus infection, human papillomavirus infection, Streptococcus pneumoniae infection, Neisseria meningitidis infection, Pneumococcal infection, viral meningitis, rotavirus infection, tick-borne encephalitis, travel diarrhea, cholera, yellow fever or tuberculosis.